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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450
UNITED STATES OF AMERICA

15 January 2008

Our Ref: 30822USS00
CWT/elp

Dear Commissioner

Speed Dial: 508**CCN: 3710000352**

United States Application No. 10/532265
D-Gen Limited
Title: Prion decontamination

Contact:

Charles Tansey, PhD

Please find attached copy of correspondence which was filed in respect of the corresponding European case. Could you please put this correspondence on file for consideration by the Examiner at the appropriate time.

Yours respectfully
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Please reply to London Office

Dear Sirs

Observations on European Patent Application No. 03769673.9
European Patent Application in the name of D-Gen Limited

We submit the following third party observations on patentability in accordance with Article 115(1) EPC.

1. New Prior Art

We would like to bring a new document to the Examiner's attention, WO 02/053723 (copy enclosed).

WO 02/053723 was published before the earliest priority date of the application-in-suit and is therefore citeable as full prior art.

2. Novelty - Article 54 EPC

WO 02/053723 discloses all the features of Claim 1 of the application-in-suit as submitted with the Applicant's letter of 8 September 2006, namely:

A method of prion decontamination of an entity comprising:
(i) contacting the entity to be decontaminated with a detergent,
(ii) contacting said entity with a first protease,
(iii) contacting said entity with a second protease,
wherein steps (i) to (iii) are performed simultaneously.

In more detail:

page 3, lines 27-28, of WO 02/053723 discloses a method of inactivating a TSE agent (which may be a prion, see page 4, lines 10-12) comprising exposing the TSE agent to a protease;

page 11, lines 23-29, of WO 02/053723 discloses the enhancement of prion degradation by combining this protease treatment with the use of a detergent, such as SDS; and

page 11, lines 23-29, of WO 02/053723 discloses the use of "combinations of proteases" instead of single enzyme treatments.

Cont'd...

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We therefore submit that WO 02/053723 discloses the simultaneous use of a detergent and two or more proteases for the prion decontamination of an entity.

Thus, Claim 1 lacks novelty over WO 02/053723.

3. Inventive Step - Article 56 EPC

We also submit that Claim 1 lacks an inventive step in accordance with the principles established by the EPO Board of Appeal in T939/92 (Agrevo).

Claim 1 requires that the entity to be decontaminated is contacted with the detergent and the two proteases simultaneously. However, there is no data in the application to support the ability of this "simultaneous" dual protease / detergent system to inactivate prions.

In fact, the application states that the simultaneous use of proteases is disadvantageous and can result in mutual digestion of the proteases, lower activity, and a longer contact time being required (see e.g. page 5, lines 28-31, and page 7, lines 23-30). It therefore recommends carrying out the protease steps sequentially rather than simultaneously (see page 7, lines 25-26), and even goes as far as to recommend that the first protease is removed completely before addition of the second protease (see page 7, lines 27-30).

Consistent with this, all of the data in the application relates to the sequential - and not the simultaneous - use of the proteases. Protocols A and B, on which all of the Examples are based, describe the serial, i.e. sequential, addition of the proteases (see page 13, lines 6-9).

In the Table attached to the Applicant's letter of 8 September 2006 (see the third box in the right-hand column of the Table), Applicant asserts that Example 1 describes the simultaneous use of the proteases. This appears to be incorrect, however, as the prions in Example 1 are treated using "Protocol A" which, as mentioned above, is a sequential and not a simultaneous use of the enzymes (see page 12, lines 24-25).

Thus, there is no credible evidence that the method of Claim 1 actually solves the technical problem addressed by the invention, i.e. there is no credible evidence that the method of Claim 1 provides an improved method of prion decontamination. Applying the principles of T939/92, the claim therefore lacks an inventive step.

4. Final Comments

We therefore submit that Claim 1 of the application-in-suit lacks novelty and / or inventive step under Articles 54 and 56 EPC and should therefore be refused.

Yours faithfully

Martin R MacLean
MATHYS & SQUIRE

Enc: WO 02/053723